

DOCKET NO.: 10248.70023US00

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Adams et al. 10/616,694

Serial No.: Confirmation No.:

1643

Filed:

July 9, 2003

For:

METHODS AND COMPOSITIONS RELATING TO

ISOLEUCINE BOROPROLINE COMPOUNDS

Examiner:

Not Yet Assigned

Art Unit:

1614

#### **CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 21 day of June, 2005.

Emily E. **Zu**kauskas

Commissioner For Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- Information Disclosure Statement
- PTO Form 1449 with cited references
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted, Adams et al., Applicant

By:

Maria A. Trevisan, Reg. No.: 48,207 Wolf, Greenfield & Sacks, P.C.

600 Atlantic Avenue

Boston, Massachusetts 02210-2206

Telephone: (617) 646-8000

Docket No.: 10248.70023US00

Date: June 27, 2005

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DOCKET NO.: I0248.70023US00

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Adams et al.

Serial No.:

10/616,694

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## CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 23th day of June, 2005.

Emily E Zukauskas

#### MAIL STOP AMENDMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

# STATEMENT FILED PURSUANT TO THE DUTY OF DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

#### PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing date of a first Office Action on the merits in the above-identified case.

No fee or certification is required.

## PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

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Conf. No.: 1643

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

Docket No.	Serial No.	Filing Date	Inventor(s)
*I0248.70026US01	11/140,508	May 27, 2004	Jesson et al.

<sup>\*</sup>a copy of this reference is not provided as the Office hereby waives the requirement under 37 CFR 1.98(a)(2)(iii) for submitting a copy of each cited U.S. patent application filed after June 30, 2003 and for applications filed before June 30, 2003, or that entered the national stage before June 30, 2003, if they are scanned to Image File Wrapper system and are available on Private PAIR.

#### PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

- 1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
- 2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
- 3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

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Conf. No.: 1643

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted, Adams et al., Applicant

Mmusan

By:

Maria A. Trevisan, Reg. No. 48,207 Wolf, Greenfield & Sacks, P.C. 600 Atlantic Avenue

Boston, Massachusetts 02210-2206

Telephone: (617) 646-8000

Docket No.: I0248.70023US00

Date: June 27, 2005

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FORM PTO-1449/A and B (Modified) 2 9 2005			APPLICATION NO.:	10/616,694	ATTY. DOCKET NO.:	I0248.70023US00	
			FILING DATE:	July 9, 2003	CONFIRMATION NO.: 1643		
			APPLICANT:	Adams et al.			
Sheet	1	of	2	GROUP ART UNIT:	1614	EXAMINER:	Not Yet Assigned

U.S. PATENT DOCUMENTS

Examiner's	Cite	U.S. Patent Doo	cument	Name of Patentee or Applicant of Cited	Date of Publication or of issue of Cited Document MM-DD-YYYY	
Initials	No.	Number	Kind Code	Document		
		2003/0130199	Al	von Hoersten et al.	07-10-2003	
	<u> </u>					

# FOREIGN PATENT DOCUMENTS

Examiner's	Cite	Foreign Patent Document			Name of Patentee or Applicant of Cited	Date of Publication of	Translation
Initials	No.	Office/ Country	Number	Kind Code	Document (not necessary)	Cited Document MM-DD-YYYY	(Y/N)
		wo	03/002595	A2	Probiodrug AG et al.	01-09-2003	
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# OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Transla (Y/N	
		Press Release, Point Therapeutics, "Point Therapeutics Announces Positive Results in Phase 2: Metastatic Melanoma Program," May 14, 2005, 3 pages.		
		Press Release, Point Therapeutics, "Point Therapeutics Presents Positive Results in Phase 2: Talabostat Non-Small Cell Lung Cancer Study," May 17, 2005, 3 pages.		
		ADAMS et al., "Enhanced Anti-Tumor Activity of Dipeptidyl Peptidase Inhibitor PT-100 in Combination with Chemotherapy in Mice," American Association of Cancer Research (AACR) Annual Meeting, Orlando, Florida, March 27-31, 2004, Poster 3820.		
		CUNNINGHAM et al., "Phase 2 Study of Talabostat and Cisplatin in Stage IV Melanoma," American Society of Clinical Oncology (ASCO) Annual Meeting, Orlando, Florida, May 14, 2005, Abstract 7563.		
		CUNNINGHAM et al., "Phase 2 Trial of Talabostat and Docetaxel in Patients with Stage IIIB/IV NSCLC," American Society of Clinical Oncology (ASCO) Annual Meeting, Orlando, Florida, May 17, 2005, Poster 7120.		

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FORM RTO 1440/4 - I R OV 11/2 10 11/11 2 9 2005			PPLICATION NO.:	10/616,694	ATTY. DOCKET NO.: 10248.70023	US00	
FORM PTO-1449/A and B (Modified) JUN 2 9 2005  INFORMATION DISCOSURE STATEMENT BY APPLICATED TO STATEM		JILING DATE:	July 9, 2003	CONFIRMATION NO.: 1643			
		APPLICANT:	Adams et al.				
Sheet	2	2 of 2		GROUP ART UNIT:	1614	EXAMINER: Not Yet As:	signed
	NEMUNAITIS et al., "A Phase 1 Trial of Talabostat (PT-100) in Patients Receiving Myelosuppressive Chemotherapy," American Society of Clinical Oncology (ASCO) Annual Meeting, New Orleans, Louisiana, June 5-8, 2004, Poster 2572.  REDMAN et al., "Phase 2 Trial of Talabostat in Stage IV Melanoma," American Society of Clinical Oncology (ASCO) Annual Meeting, Orlando, Florida, May 14, 2005, Abstract 7570.						
	- One	оюду	(ASCO) Anuda	i wooting, Oriando, i k	Jildu, Way 14, 20	00, 1100Havt 1310.	

EXAMINER:	DATE CONSIDERED:

#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[NOTE - The Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC 371 after June 30, 2003. See 37 CFR 1.491(b). For all patent applications filed on or before June 30, 2003, copies of cited U.S. patents and patent application publications are still required unless an eIDS is filed. Copies of all other patent(s), publication(s), or other information listed must still be provided, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]

<sup>\*</sup>a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_\_, filed \_\_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).